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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,148	03/06/2000	Robert J. Lipshutz	18547-009911	7804

7590 06/13/2002

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/13/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/519,148

Applicant(s)

LIPSHUTZ ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80-124 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80-124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634, and has been assigned to Primary Examiner Bradley L. Sisson.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 March 2002 has been entered.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1634

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 80-110, 112-114, and 116-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al., (US Patent 5,304,487; hereinafter "Wilding 1"), in view of Staecker et al., and Wilding et al., (US Patent 5,587,128; hereinafter "Wilding 2").

7. Wilding 1 discloses a method for analyzing a sample in an integrated microfluidic device that has a plurality of chambers that are in fluid communication with each other. As seen in column 2, the diameter of the channels can range from 0.1 μm to 500 μm . Said channels are in communication with "fluid handling regions." Said regions are considered to meet the limitation of applicants "at least two chambers." Column 3 discloses that the results can be detected through a window, and that such detection includes the use of detectable moieties. Column 9 discloses the optional use of additional components for detecting/viewing the assay results. The aspect that the resultant signal can be viewed through a window is considered to meet the limitation that the "reader" is outside of the chamber (a limitation of independent claims 80 and 93, and claims 81-92, 94-105, 110-124 that depend therefrom).

Art Unit: 1634

8. Column 4, first paragraph, teaches explicitly of the optional use of valves within the fluid communication means.
9. The use of the device in the analysis of nucleic acids, be it DNA or RNA is explicitly taught at column 6. The use of detectable moieties in combination with DNA probes, as in nucleic acid assays, is disclosed at column 7.
10. Wilder 1 does not disclose the use of confocal microscopy; nor the use of electrophoretic separation of nucleic acid fragments.
11. Wilding 2, which is based upon a CIP application that matured into Wilding 1, teaches the use of the device in the analysis of nucleic acids, including the amplification of sequences. The use of arrays in concert with the detection of target sequences is disclosed (column 24).
12. While Wilding 2 does teach the use of readers/detection means that are placed internal to the device, it is also noted that Wilding 2 explicitly teaches that one can detect the signal, e.g., a fluorescent signal, "either visually or by machine, through a transparent window disposed over the detection region." Bif
13. Wilding 2, column 20, penultimate paragraph, teaches performing electrophoretic separation of nucleic acid sequences. The performance of electrophoretic separation speaks directly to separating the nucleic acid sequences according to size.
14. Wilding 2 does not teach the use of confocal microscopy.
15. Steacker et al., teach of an assay wherein nucleic acids are subjected to amplification and the resultant amplification product is detected/studied through the use of confocal microscopy.
16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method and device of Wilder 1 and Wilder 2 so to utilize

Art Unit: 1634

confocal microscopy as taught by Steacker et al. Motivation for performing confocal microscopy on an amplification product is found at page 76, right column, where it is taught that this procedure allows for the detection of minute quantities of mRNA and avoids the time-consuming process of autoradiography.

17. Claims 111 and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding 1, Wilding 2, and Staecker et al., as applied to claims 80-110, 112-114, and 116-124 above, and further in view of Brelje et al.

18. Brelje et al., teach at length of the advantages of performing scanning confocal microscopy, including where nucleic acids are being studied. Table 2, column 10, teaches explicitly of DNA specific stains (Chromomycin A3) as well as the use of fluorescein the same fluorophores used by Staecker et al.

19. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Wilder 1, Wilder 2, and Staecker et al., with the method of Brelje et al., so that scanning form of confocal microscopy was used. As set forth in columns 1 and 2, confocal microscopy is well known in the art, yet the aspect of performing scanning confocal microscopy has been found to improve on the design of confocal microscopy. In view of the explicit guidance to use scanning confocal microscopy, and in view of the well-developed nature of confocal microscopy as well as performing nucleic acid assays in integrated microfluidic devices, the ordinary artisan would have been both sufficiently motivated and expectant of success in performing such a combination.

Art Unit: 1634

20. For the above reasons, and in the absence of convincing evidence to the contrary, the invention of claims 80-124 is considered to be obvious in view of the prior art of record.

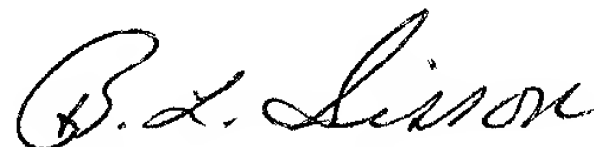
Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

23. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
June 11, 2002